EXHIBIT 1

REDACTED

EXHIBIT 2

REDACTED

EXHIBIT 3

REDACTED

EXHIBIT 4

REDACTED

EXHIBIT 5

REDACTED

EXHIBIT 6

REDACTED

EXHIBIT 7

1 of 4 DOCUMENTS

Caution
As of: Apr 30, 2007

CENTRAL ADMIXTURE PHARMACY SERVICES, INC. and DR. GERALD D. BUCKBERG, Plaintiffs-Appellees, v. ADVANCED CARDIAC SOLUTIONS, P.C. and CHARLES WALL, Defendants-Appellants.

2006-1307

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2007 U.S. App. LEXIS 7593

April 3, 2007, Decided

PRIOR HISTORY: [*1] Appealed from: United States District Court for the Northern District of Alabama. Judge Virginia Emerson Hopkins. *Cent. Admixture Pharm. Servs. v. Advanced Cardiac, 2006 U.S. Dist. LEXIS 95833 (N.D. Ala., Jan. 10, 2006)*

COUNSEL: Brett J. Williamson, O'Melveny & Myers LLP, of Newport Beach, California, argued for plaintiffs-appellees. With him on the brief was Nathaniel L. Dilger.

Robert J. Veal, Smith, Gambrell & Russell, LLP, of Atlanta, Georgia, argued for defendants-appellants. With him on the brief was Brendan E. Squire.

JUDGES: Before SCHALL, GAJARSA, and PROST, Circuit Judges.

OPINION BY: GAJARSA

OPINION: GAJARSA, Circuit Judge.

In this patent infringement case, defendants Advanced Cardiac Solutions and Charles Wall (collectively "ACS") appeal from several summary judgment orders issued by the United States District Court for the Northern District of Alabama. The district court found ACS liable to plaintiffs Central Admixture Pharmacy Services ("CAPS") and Dr. Gerald Buckberg for willful infringement of *U.S. Patent No. 4,988,515 ("the '515 patent")*, and dismissed ACS's counterclaims of false marking and false advertisement. Because the certificate of correction CAPS obtained from the U.S. Patent and Trademark Office ("PTO") to alter the asserted claims of the *'515 patent* is invalid, we [*2] vacate the finding of infringement and remand for a redetermination of infringement under the patent's original, uncorrected claims. We affirm the district court's summary judgment findings that the patent is not invalid and that CAPS did not commit false marking or false advertisement, as well as the court's procedural rulings with respect to ACS's defenses of inequitable conduct and patent misuse.

I. BACKGROUND

A. The Technology and Patent

The patent at issue claims a chemical solution used during heart surgery. If blood supply to the heart is interrupted during surgery, lack of fresh blood ("ischemia") will, untreated, cause cardiac tissue to die. *'515 patent* col.1 ll.11-22. The patented solution contains glucose and amino acids to nourish the heart tissue even without a continuous supply of blood, allowing surgeons to operate on the heart for longer periods of time.

The patent has claims directed to the solution and to methods of treatment using the solution. For the purposes of the issues we reach on this appeal, Claim 1 is representative. That claim initially read:

> In an amino acid enriched cardioplegic solution for use in treating human hearts to prevent [*3] or reverse heart muscle damage due to ischemia, said cardioplegic solution having a calcium ion concentration, a metabolizable substrate concentra-

> tion and an osmolarity, wherein the improvement comprises:
>
> maintaining said calcium ion concentration of said cardioplegic solution at a lowered level of between about 50-300 umol;
>
> maintaining said concentration of metabolizable substrate in said cardioplegic solution between about 400-1000 mg % wherein said metabolizable substrate is selected from the group consisting of glucose, fructose, a salt of malic acid, a salt of succinic acid and a salt of pyruvic acid; and
>
> maintaining said osmolarity of said cardioplegic solution at an increased level of between about 400-500 mOsmol.

'515 patent col.8 l.56 to col.9 l.5 (emphasis added).

B. The Certificate of Correction

On December 15, 1999, CAPS applied, pursuant to *35 U.S.C. § 255*, for a certificate of correction to replace all instances of the word "osmolarity" in the *'515 patent* with the word "osmolality."

Section 255 provides:

> Whenever a mistake of a clerical or typographical nature, or of minor character, which was not [*4] the fault of the Patent and Trademark Office, appears in a patent and a showing has been made that such mistake occurred in good faith, the Director may, upon payment of the required fee, issue a certificate of correction, if the correction does not involve such changes in the patent as would constitute new matter or would require re-examination. Such patent, together with the certificate, shall have the same effect and operation in law on the trial of actions for causes thereafter arising as if the same had been originally issued in such corrected form.

On January 30, 2001, after the complaint in this lawsuit was filed, the PTO issued the requested certificate. The two terms, which each describe the concentration of a chemical solution contributing to that solution's osmotic pressure, are related but subtly different in meaning. "Osmolarity" refers to the amount of solute (dissolved chemical) per liter of total solution. At the concentrations involved in this case, osmolarity is measured in milliosmoles per liter (mOsmol/L). In contrast, "osmolality" refers to the amount of solute per kilogram of solvent. It is measured in milliosmoles per kilogram (mOsmol/kg). [*5] Osmolality can be more-or-less directly measured and calculated using a device called an osmometer, which computes osmolality from the depression of the solution's freezing point. Osmolarity is derived from the osmolality figure.

As highlighted above, the asserted patent claims initially required the solution to have an "osmolarity . . . of between about 400-500 mOsmol," but after the certificate issued, the claims required an "osmolality . . . of between about 400-500 mOsmol." n1 (emphasis added). For the solutions at issue here, the numerical figure for osmolarity will be less than the figure for osmolality by about one or two percent. n2 The result of this change is to cause the claimed concentration range to shift slightly downwards, covering less-concentrated solutions near the low end of the claimed range and ceasing to cover more-concentrated solutions near the high end. All of the allegedly infringing solutions have concentrations near the low end of the claimed range. Because of the change in the range, it is more likely that the accused solutions infringe the corrected claims, while they may not have infringed the original claims.

> n1 Both before and after correction, the claims indicated units of "mOsmol," (a measurement of quantity, not concentration) rather than "mOsmol/L" (the units of osmolarity) or "mOsmol/kg" (osmolality). Under either the "osmolarity" or "osmolality" version of the claim, the choice of unit is technically incorrect. The correct denominator depends on which of the two terms is used.

[*6]

> n2 As an example, CAPS provides a chart in its brief that converts between the measured osmolality and computed osmolarity of various accused solutions. The solution described in the chart's top-left cell has an osmolality of 391 mOsmol/kg and an osmolarity of 382 mOsmol/L.

C. Dr. Buckberg's Dealings with UC and NIH

The research that led to the *'515 patent* was conducted under a grant awarded by the National Institutes of Health ("NIH") to Dr. Buckberg's employer, the University of California ("UC"). *'515 patent* col.1 ll.23-25.

The government therefore has certain rights with respect to the patent under the Bayh-Dole Act, *35 U.S.C. §§ 200-212*, including the right to be notified of the invention, id. *§ 202(c)(1)*, to obtain patents in foreign countries where the inventor does not pursue patent applications, id. *§ 202(c)(3)*, a royalty-free nonexclusive license, id. *§ 202(c)(4)*, and the ability under certain circumstances to "march-in" and compel the patentee to grant a license to a third party, id. *§ 203*.

During patent prosecution, Dr. Buckberg designated UC as his assignee. On February 12, 1987, UC [*7] communicated to NIH its intent to abandon its interest in the pending application. One month later, Dr. Buckberg wrote to NIH to request that it waive patent rights in the application so that he could pursue the application in his personal capacity. See *35 U.S.C. § 202(d)* (allowing agencies to grant such requests). NIH granted that waiver on September 23, 1987, on the condition that "the inventor shall grant to the Government of the United States a nonexclusive, irrevocable, royalty-free license to use the invention for governmental purposes. . . . This determination will become effective upon receipt of the executed copy [of the license]." Dr. Buckberg made an admission under *Fed. R. Civ. P. 36* that he never executed the requested license. n3 The patent issued on January 29, 1991. On June 24, 1991, UC assigned its interest in the *'515 patent* to Dr. Buckberg. The same day, Dr. Buckberg exclusively licensed the patent to CAPS.

> n3 However, the patent's written description recognizes, as required by *35 U.S.C. § 202(c)(6)*, that the invention was made with support from NIH funding and that "[t]he Government has certain rights in this invention." *'515 patent* col.1 ll.23-26.

[*8]

D. Litigation History

On August 31, 2000, CAPS filed this infringement suit. Dr. Buckberg later joined as a plaintiff. In an order dated January 13, 2006, the district court disposed of most of the issues in the case. It found that the plaintiffs had standing to bring this suit, granted summary judgment to the plaintiffs that the patent was not invalid and that the plaintiffs had not committed false marking or false advertising, and dismissed the defendants' inequitable conduct defense on the pleadings. It also granted to the plaintiffs conditional summary judgment of infringement and willfulness for actions occurring after the issuance of the certificate of correction, contingent upon the certificate being found valid. The district court later determined that the certificate was valid as a matter of law. The plaintiffs then withdrew their claims of infringement for acts prior to the issuance of the certificate, making the district court's infringement and willfulness judgments final as to all acts of infringement still alleged by the plaintiffs. ACS timely appealed to this court.

II. DISCUSSION

A. Standing

ACS argues that CAPS lacks standing to bring this [*9] action because, as a result of Dr. Buckberg's failure to execute the license required by NIH, neither CAPS nor Dr. Buckberg have rights to the *'515 patent*. If ACS is correct, this action must be dismissed since only the patent owner or the holder of all substantial rights under the patent may sue for infringement. See *Propat Int'l Corp. v. RPost, Inc., 473 F.3d 1187, 1189-93 (Fed. Cir. 2007)*; *Fieldturf, Inc. v. Sw. Recreational Indus., 357 F.3d 1266, 1268-70 (Fed. Cir. 2004)*; *Speedplay, Inc. v. Bebop, Inc., 211 F.3d 1245, 1249-52 (Fed. Cir. 2000)*; *Rite-Hite Corp. v. Kelley Co., 56 F.3d 1538, 1551-52 (Fed. Cir. 1995)* (en banc).

As an initial matter, Dr. Buckberg admitted pursuant to *Fed. R. Civ. P. 36* that he did not execute the license to NIH. He later sought to retract that admission, but the district court refused to allow him to do so. That refusal was not an abuse of discretion, so the fact that Dr. Buckberg did not execute the license is for the purposes of this case "conclusively established." *Fed. R. Civ. P. 36(b)*.

We discussed [*10] the consequences of a patentee's failure to comply with the requirements of the Bayh-Dole Act in *Campbell Plastics Engineering & Manufacturing, Inc. v. Brownlee, 389 F.3d 1243 (Fed. Cir. 2004)*. In that case, an Army contractor working under a cost-plus-fixed-fee contract developed an invention during the course of its work. *Id. at 1244*. The contract incorporated by reference regulation *48 C.F.R. § 52.227-11*, n4 which requires that a contractor disclose to the government inventions made pursuant to the contract. Id. The contractor in Campbell Plastics did not disclose that it had developed patentable subject matter, *id. at 1245*, but obtained a patent on the invention, *id. at 1246*. An Administrative Contract Officer with the Army demanded title to the invention, and the Armed Services Board of Contract Appeals ("ASBCA") affirmed. *Id. at 1244*. We affirmed the ASBCA, finding that the contractor's failure to disclose the invention as provided in the contract "afforded the government the opportunity to take title to its patent." *Id. at 1249*. The government [*11] chose to exercise its right pursuant to the regulations, and as a result, title to the patent was forfeited to the government. *Id. at 1250*.

n4 The regulation at issue in Campbell Plastics is in relevant part substantially the same as *37 C.F.R. § 401.14*, which was incorporated into the grant agreement between UC and NIH. Compare *48 C.F.R. § 52.227-11* with *37 C.F.R. § 401.14*.

Critically, Campbell Plastics holds that a Bayh-Dole violation grants the government discretionary authority to take title. *Id. at 1250* (regulation "vests discretion in the government in determining whether to invoke forfeiture when an invention has not been correctly disclosed to it." (emphasis added)). When a violation occurs, the government can choose to take action; thus, title to the patent may be voidable. However, it is not void: title remains with the named inventors or their assignees. Nothing in the statute, regulations, or our caselaw indicates that title is automatically forfeited. The government must take an affirmative action to establish [*12] its title and invoke forfeiture. The defendants here have no basis to challenge the government's discretion in not invoking forfeiture.

It may be that Dr. Buckberg's failure to execute the required license enables NIH to exercise its discretion to void his title in the *'515 patent* -- a question we assuredly do not decide today. However, NIH has shown no interest in pursuing the matter. Absent any action by NIH, Dr. Buckberg retains title to the patent and his exclusive license to CAPS is valid. The two plaintiffs together own all present rights in the *'515 patent*, providing them standing to bring the action. Since the district court's infringement judgment is final as to all issues except for a determination of damages, we have jurisdiction under *28 U.S.C. § 1292(c)(2)*. See *Mendenhall v. Barber-Greene Co., 26 F.3d 1573, 1581 (Fed. Cir. 1994)*.

B. The Certificate of Correction

A patentee who has made "a mistake of a clerical or typographical nature, or of minor character" may apply to the PTO for a "certificate of correction, if the correction does not involve such changes in the patent as would constitute new matter or would require [*13] reexamination." *35 U.S.C. § 255*. We have previously interpreted this statutory provision in *Superior Fireplace Co. v. Majestic Products Co., 270 F.3d 1358 (Fed. Cir. 2001)*. Superior Fireplace held that if a certificate of correction broadens a claim, it is only valid if it corrects a "clerical or typographical" error that would have been clearly evident to one of skill in the art reading the intrinsic evidence. *Id. at 1373* ("[W]e interpret *§ 255* to require that a broadening correction of a clerical or typographical error be allowed only where it is clearly evident from the specification, drawings, and prosecution history how the error should appropriately be corrected."); *id. at 1375* ("A mistake that, if corrected, would broaden the scope of a claim . . . cannot be a mistake of 'minor character.'"). Since the result is to invalidate a certificate of correction which is part of a duly issued patent, the party seeking invalidation must meet "the clear and convincing standard of persuasion." *Id. at 1367*.

Invalidating a certificate of correction for impermissible broadening therefore requires [*14] proof of two elements: (1) the corrected claims are broader than the original claims; and (2) the presence of the clerical or typographical error, or how to correct that error, is not clearly evident to one of skill in the art. The first element poses a question of law, since the correct scope and meaning of a claim is an issue for the court to decide. See *Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995)* (en banc), aff'd, *517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996)*; see also *Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454-56 (Fed. Cir. 1998)* (en banc). To answer the question of whether a claim has been broadened through correction requires interpreting the old and new versions of that claim, and then determining whether the new version covers territory the old one did not. This same inquiry has been treated as a question of law in *§ 251* reissue cases, and should be treated as such in the *§ 255* context as well. See *MBO Labs., Inc. v. Becton, Dickson & Co., 474 F.3d 1323, 1332 (Fed. Cir. Jan. 24, 2007)*; *In re Clement, 131 F.3d 1464, 1468 (Fed. Cir. 1997)* (deciding [*15] as a matter of law "whether and in what aspect the reissue claims are broader than the patent claims"). We find that these claims were broadened by the certificate of correction, since the claims as corrected cover less-concentrated solutions which would not be covered under the original claims.

The second element, whether the error and its correction would both be clearly evident to one of skill in the art, has been treated as a factual question. See *ArthroCare Corp. v. Smith & Nephew, Inc., 406 F.3d 1365, 1374-75 (Fed. Cir. 2005)* (reviewing jury verdict for substantial evidence); *Superior Fireplace, 270 F.3d at 1373* (reviewing district court's summary judgment for "a genuine issue"). ACS moved for judgment that the certificate of correction was invalid, but the district court ruled as a matter of law that the certificate was valid. Summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *Fed. R. Civ. P. 54(c)* [*16] .

Superior Fireplace posits three categories into which an error might fall. The first category involves "mistakes [that] are immediately apparent and leave no doubt as to what the mistake is." *Id. at 1370*. This category includes

"misspellings that leave no doubt as to the word which was intended; 'frane' instead of 'frame,' for example." Id. This category also extends to clerical errors in which the patentee attempts to change every instance of a particular claim term in prosecution but misses one, leaving a claim that, on its face, is nonsensical in light of the specification. In such cases, one of skill in the art would know from the prosecution history that the patentee had missed one term and would know that the proper correction would be to change that term as well. *ArthroCare, 406 F.3d at 1374-75*.

Since an error of the first category makes its own correction known to one of skill in the art, those errors do not raise serious public notice problems and can properly be corrected via a *§ 255* certificate.

> In contrast, a second category includes those typographical mistakes not apparent to the reader at all; for example, a mistake [*17] resulting in another word that is spelled correctly and that reads logically in the context of the sentence. A third category of mistakes includes those where it is apparent that a mistake has been made, but it is unclear what the mistake is.

Superior Fireplace, 270 F.3d at 1370. "It is not evident to the reader of the public record how to appropriately correct mistakes of the second and third categories," id., so those categories of error cannot be repaired via a certificate of correction if the effect would be to broaden the claim.

The undisputed facts demonstrate that the error here is one of the second category. The word 'osmolarity' is indeed "spelled correctly and reads logically in the context of the sentence." Id. All solutions of the type described have a calculable osmolarity, and to one of skill in the art, a concentration of about 400-500 mOsmol/L is not a manifestly erroneous one. n5 The patentee specified a particular unit of measure for his claim. That unit measures the appropriate property (chemical concentration) and the claimed range is, as demonstrated by the written description, generally effective for the stated purpose. The fact [*18] that the unit of measure that the patentee indicated is not the most conventional or convenient is of limited significance. n6 Claims mean precisely what they say. Cf. *Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005)* (en banc) ("[W]e look to the words of the claims themselves . . . to define the scope of the patented invention." (emphasis added)) (quoting *Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)).*

> n5 The result might be different if the patentee's choice of unit resulted in a clearly incorrect claim -- "fifty miles" instead of "fifty meters," for instance. Here, though, the difference between an osmolarity of 400 mOsmol/L and an osmolality of 400 mOsmol/kg is very slight.

> n6 CAPS' technical expert testified that because osmolarity cannot be measured as directly as osmolality, one of skill in the art "could discern" that a mistake had occurred. However, Superior Fireplace does not allow the mere possibility that one of skill in the art might perceive an error to support a broadening correction. Instead, it must be "clearly evident from the specification, drawings, and prosecution history how the error should appropriately be corrected." *270 F.3d at 1373* (emphasis added).

[*19]

Since the error corrected here was not clearly evident to one of skill in the art and the result of its correction was to broaden the claims, ACS should be granted summary judgment that the certificate of correction is not valid. The patent therefore continues to read as it did prior to the issuance of the certificate. See *Superior Fireplace, 270 F.3d at 1367* ("[I]nvalidation of the certificate of correction result[s] in [the] uncorrected claim . . . being restored.").

Because the district court's summary judgments of infringement and willfulness were both explicitly contingent on the validity of the certificate of correction, both of those judgments are vacated. On remand, the infringement inquiry should proceed under the original "osmolarity" versions of the claims. n7

> n7 Since the findings of infringement and willfulness are vacated on the ground that the certificate of correction is invalid, we do not reach ACS's arguments relating to CAPS' infringement tests of the accused products, secondary infringement, prosecution history estoppel, or the opinion of counsel ACS alleges it relied on to defeat willfulness.

C. Claim Construction [*20]

The district court construed the phrase "osmolality . . . of between about 400-500 mOsmol" in the corrected claims to allow for an osmolality between 385-515 mOsmol/kg. Since that construction interprets language that is not validly part of the claims, it cannot stand exactly as issued. However, the correct construction of the originally issued claims is basically the same, except for the substitution of units: "osmolarity . . . of between about 400-500 mOsmol" encompasses osmolarities as low as 385 mOsmol/L. Rather than basing this broadening of the enumerated range on the alleged interchangeability of the terms "osmolarity" and "osmolality," as the district court did, we base it on the presence of the word "about" in the claim.

> The use of the word "about[]" avoids a strict numerical boundary to the specified parameter. Its range must be interpreted in its technological and stylistic context. We thus consider how the term was used in the patent specification, the prosecution history, and other claims. It is appropriate to consider the effects of varying that parameter, for the inventor's intended meaning is relevant. Extrinsic evidence of meaning and usage in the art may [*21] be helpful in determining the criticality of the parameter.

Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd., 476 F.3d 1321, 1326 (Fed. Cir. 2007) (ellipses omitted) (quoting *Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1217 (Fed. Cir. 1995))*. Here, the intrinsic evidence indicates that the overall osmolarity of the solution is crucial to its effectiveness, and that osmolarities over 400 mOsmol/L are most consistently effective. See *'515 patent* Figs. 2-3. However, that evidence also shows that osmolarities below 400 mOsmol/L are effective. The patent's Figure 2 details the result of an experiment measuring the effect of solution osmolarity on systolic shortening, an indicator of the health of cardiac tissue. The figure makes clear that as osmolarity increases from about 360 mOsmol/L to about 480 mOsmol/L, systolic shortening improves. It includes a trend line that extrapolates a linear relationship between osmolarity and shortening; that line crosses the figure's x-axis near to 385 mOsmol/L, indicating that the break-even point for effectiveness is found close to that concentration. Since the intrinsic evidence indicates [*22] that the solution begins to be effective near a concentration of 385 mOsmol/L, the word "about" extends the range of the claim downward to that point.

ACS also argues that the district court erred by failing to construe the term "maintaining" in Claims 7-12. The district court found that ACS waived any argument with respect to this term by failing to raise it during the claim construction phase. We agree. Since ACS has not preserved this argument before the district court, we do not reach it here.

Finally, ACS suggests that the patent's Claim 13 and its dependent claims are invalid for indefiniteness, since they describe a solution that is "adapted to be diluted." We do not read that phrase as possessing any significant ambiguity, much less intractable ambiguity making the claim "not amenable to construction," which is the requirement to demonstrate indefiniteness. *Aero Prods., Inc. v. Intex Rec. Corp., 466 F.3d 1000, 1016 (Fed. Cir. 2006)*.

D. Inequitable Conduct

The district court dismissed ACS's defense that the patent was unenforceable due to inequitable conduct because ACS failed to plead that conduct with particularity. Whether inequitable conduct [*23] has been adequately pled is a procedural matter, but since it bears on an issue that "pertains to or is unique to patent law," we will apply our own law to the question of whether the pleadings were adequate. See *Intel Corp. v. Commonwealth Sci. & Indus. Research Org., 455 F.3d 1364, 1369 (Fed. Cir. 2006)*.

We have held that "inequitable conduct, while a broader concept than fraud, must be pled with particularity." *Ferguson Beauregard/Logic Controls, Inc. v. Mega Sys., LLC, 350 F.3d 1327, 1344 (Fed. Cir. 2003)*. ACS pleaded inequitable conduct by alleging only that "during prosecution of the *'515 patent*, the patentee failed to disclose all of the relevant prior art known to it" and that "by manipulation of various measurements and units, the patentee sought to mislead the Patent and Trademark Office regarding the relationship between the claimed invention and the prior art." Defendants' Third Amended Answer (N.D. Ala. Mar. 16, 2005). This pleading lacks the requisite particularity. It does not identify what relevant and undisclosed prior art was known to the patentee, what "measurements and units" were manipulated, or how that manipulation [*24] was meant to mislead the PTO. n8 The pleading thus fails to provide the required particularity to give notice to the other party of the facts on which the defense is premised, and it was properly dismissed by the district court.

> n8 This is not to suggest that the PTO must actually rely on a prosecution statement or omission in order for that statement to be material in the context of inequitable conduct. See *C.R.*

Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1365 (Fed. Cir. 1998).

ACS sought to amend this element of its pleadings, but the district court refused to grant it leave to amend. ACS appeals the denial. We apply the procedural law of the Eleventh Circuit, which reviews denials of leave to amend an answer for abuse of discretion. *Hall v. Aetna Cas. & Sur. Co., 617 F.2d 1108, 1110 (11th Cir. 1980).* No such abuse is present here. ACS's attempt to amend its pleadings came on December 27, 2004, over three years after the close of discovery. The district court correctly noted that ACS's amended answer would "require the parties to conduct new discovery, including entirely new expert discovery, thereby essentially reopening a case [*25] that has been pending since 2000." Order Striking Answer, Cent. Admixture Pharm. Servs., Inc. v. Advanced Cardiac Solutions, P.C., No. 00-CV-2430 (N.D. Ala. Mar. 3, 2005). The district court's authority to manage discovery is broad enough to place this ruling within its sound discretion.

Since ACS did not properly plead inequitable conduct and cannot now amend its answer to do so, inequitable conduct is not part of this case on remand.

E. Validity

The district court's summary judgment of no invalidity disposed of several arguments by ACS. ACS has appealed on only two grounds: it argues that the claims are indefinite and that the asserted claims are barred under *35 U.S.C. § 102(b)* by certain clinical trials allegedly performed by Dr. Buckberg more than one year before the patent application was filed on August 21, 1985. We addressed and rejected the indefiniteness argument in Part II.C., supra. The district court's *§ 102(b)* finding would be affirmed whether the claims read "osmolarity" or "osmolality," so we resolve this issue now rather than remanding it.

The Supreme Court has held that "[t]he plain language of [*Federal] Rule [of Civil Procedure] 56(c)* [*26] mandates the entry of summary judgment . . . against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett, 477 U.S. 317, 322, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986).* The only evidence ACS presents to demonstrate a bar under *§ 102(b)* is a scientific article co-authored by Dr. Buckberg describing a study of his cardioplegic solution conducted on patients between May 1984 and April 1985. Part of that period -- between an unspecified day in May 1984 and August 20, 1984 -- falls more than one year before the application for patent. The article is totally nonspecific, though, as to what type of surgical activity occurred before August 21, 1984, and ACS has presented no other evidence whatsoever that any surgeries using the claimed invention actually took place before that critical date. The alleged infringer bears "the burden of proving invalidity by clear and convincing evidence." *U.S. Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1564 (Fed. Cir. 1997)*; see also *Abbott Labs. v. Baxter Pharm. Prods., Inc., 471 F.3d 1363, 1367 (Fed. Cir. 2006)*; [*27] *Typeright Keyboard Corp. v. Microsoft Corp., 374 F.3d 1151, 1157 (Fed. Cir. 2004).* On this very sketchy record, no reasonable jury could find by clear and convincing evidence that the described surgeries using the claimed invention occurred prior to the critical date. Since ACS has failed to meet its burden of coming forward with evidence to create a genuine dispute of fact on this issue, we affirm the summary judgment without reaching CAPS' argument that any surgeries performed during the study were experimental in nature.

We have rejected all of ACS's arguments on appeal that the asserted claims are invalid. ACS has not preserved any of its other validity arguments, so on remand validity is not at issue.

F. ACS's counterclaims

The district court granted summary judgment to CAPS on ACS's counterclaims for false marking and false advertisement. There is no error in either of these determinations, and we affirm the district court. It also refused to allow ACS to amend its answer to introduce a counterclaim for patent misuse. For the reasons discussed in Part II.D., supra, the district court did not abuse its discretion by prohibiting that amendment. [*28]

III. CONCLUSION

We reverse the district court's finding that the certificate of correction applied to the *'515 patent* is valid. The district court's summary judgment of infringement is therefore vacated. We affirm the district court's summary judgments that the patent is not invalid and that there is no liability for false marking or false advertisement, its decision not to allow ACS to file an amended answer raising patent misuse or alter its pleadings with respect to inequitable conduct, and its dismissal of ACS's inequitable conduct defense. On remand, CAPS may pursue its allegations of infringement of the uncorrected "osmolarity" version of the *'515 patent* claims.

AFFIRMED-IN-PART, REVERSED-IN-PART, VACATED-IN-PART, and REMANDED

No costs.

EXHIBIT 8

United States Patent [19]

Isaac

[11] **Patent Number: 4,770,422**

[45] **Date of Patent: * Sep. 13, 1988**

[54] **COMPOSITION FOR MAKING DURABLE GOLF BALLS AND OTHER PRODUCTS**

[75] Inventor: **Sharon R. Isaac**, Acushnet, Mass.

[73] Assignee: **Acushnet Company**, New Bedford, Mass.

[*] Notice: The portion of the term of this patent subsequent to Oct. 15, 2002 has been disclaimed.

[21] Appl. No.: **794,164**

[22] Filed: **Nov. 1, 1985**

[51] **Int. Cl.**[4] **C08L 9/00**; C08L 35/02; A63B 37/00; A63B 37/02

[52] **U.S. Cl.** ..... **273/218**; 273/228; 273/230; 273/235 R; 525/263; 525/265; 525/274; 524/908; 524/533

[58] **Field of Search** ..... 525/274, 263, 265, 193, 525/195, 196; 524/908; 273/218, 228, 230, 235 R

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Primary Examiner—Allan M. Lieberman
Attorney, Agent, or Firm—Lucas & Just

[57] **ABSTRACT**

A composition for making golf ball products is disclosed. Polybutadiene is crosslinked by zinc diacrylate with the use of a free radical initiator, such as a peroxide. The amount of free radical initiator used is between 0.2 parts and 0.8 parts per 100 parts polybutadiene. The amount of zinc diacrylate and free radical initiator are controlled and the curing conditions adjusted so that the golf ball product has a swell index of at least about 0.6 and a PGA compression of about 50–110.

65 Claims, No Drawings

COMPOSITION FOR MAKING DURABLE GOLF BALLS AND OTHER PRODUCTS

The present invention relates to golf balls and in particular to a composition for making durable solid golf ball products which still have good playing characteristics such as good initial velocity.

As used in the industry, the term "solid golf balls" refers to balls which do not have windings, i.e. they are either unitary, one piece golf balls or are multiple piece golf balls, e.g. with a solid unitary core and a separate cover.

For many years golf balls were made by winding a very long elastic thread about a center, which was either a solid or a liquid-filled balloon, and then molding a cover, notably of balata, thereabout. This is both a laborious and time consuming process and involves substantial expense. Because of this, manufacturers have been continually trying to reduce the complexity and cost of making a golf ball.

In the 60's it was thought that this had been accomplished with the inventions of James R. Bartsch, whose inventions are set forth in U.S. Pats. Nos. 3,438,933 and 3,313,545. The Bartsch patents teach a polymer backbone crosslinked by one or more organic monomers and these chemical compositions certainly had the greatest promise to that time of making a one piece solid golf ball. Many manufacturers spent millions of dollars trying to develop a successful commercial golf ball utilizing the Bartsch technology. While some golf balls did reach the marketplace, they were almost universally condemned because of their poor performance, particularly in terms of low initial velocity. By the early 70's, golf balls of this type had virtually, if not completely, disappeared from the marketplace except for unique situations such as golf driving ranges where poor initial velocity is considered desirable by the operator since it makes it less likely that golf balls will be hit so far that they are lost.

In the early 70's it was discovered that golf balls could be made by crosslinking polymers, typically polybutadiene, with metal salts of unsaturated carboxylic acids, notably zinc diacrylate or zinc dimethacrylate, and that such compositions were substantially better than the Bartsch composition in terms of golf ball properties such as initial velocity, rebound and the like. Balls made with zinc diacrylate as the crosslinker have higher initial velocity than those made with zinc dimethacrylate. However, balls made with zinc diacrylate as the crosslinker lacked the important element of durability. In boxing terms, they were similar to a fighter with a "glass jaw", i.e. if they were hit hard enough, they would fall apart. A number of manufacturers saw the advantage of using this technology, however, and toughened up the golf ball by putting on a cover of Surlyn resin, an ionomer made by duPont. While these balls were quite good, they lacked the advantage of being capable of producing one piece balls. Additionally, even as two piece solid balls, there was a tendency for the core to crack, especially where the polymer was polybutadiene cross-linked by a zinc diacrylate.

In the manufacture of golf ball products by crosslinking of a polymer such as polybutadiene with a metal salt of an unsaturated carboxylic acid such as zinc diacrylate or zinc dimethacrylate, as a practical matter it is necessary to include a free radical initiator to promote the reaction. The free radical initiator is generally used in the amount of 2–7% by weight of the polymer material.

The applicants have now discovered that an improved golf ball product comprising polybutadiene crosslinked by zinc diacrylate can be made if the amount of free radical initiator is substantially below that typically used in the past. The golf ball product is characterized by excellent durability as well as good initial velocity.

In accordance with the present invention the total amount of free radical initiator used in making a golf ball product is from about 0.2% to about 0.8% by weight of the polybutadiene. It is preferred to use about 0.2% to 0.5% since this results in a golf ball product with good compression and it is most preferred to use about 0.2%.

The term free radical initiator as used herein refers to a chemical which, when added to an admixture of polybutadiene and a metal salt of an unsaturated carboxylic acid, promotes the crosslinking of the polybutadiene by the metal salt of the unsaturated carboxylic acid. Typical of these free radical initiators are peroxides such a dicumyl peroxide.

The term golf ball product is generic and includes unitary golf balls, cores of two piece golf balls, centers of wound golf balls and the like. The present invention may be used to form a unitary golf ball or a two or more part golf ball if desired. The composition of the present invention may be used for either the core or the shell cover of a two piece ball but best results are obtained when the composition of the present invention is used as the core with a standard cover such as of Surlyn ionomer resin.

The preferred free radical initiators are peroxides. Suitable peroxides are dicumyl peroxide, 1,1-di-(t-butylperoxy)-3,3,5-trimethyl cyclohexane, t-butyl perbenzoate, n-butyl-4,4-bis-(t-butylperoxy) valerate, 1,1-di(t-butylperoxy) cyclohexane, ethyl-3,3-di(t-butylperoxy) buterate, α,α'-bis-(t-butylperoxy)diisopropyl benzene, and t-butylcumyl peroxide.

A typical base composition in accordance with the present invention comprises polybutadiene and, in parts by weight based on 100 parts polybutadiene, 25–40 parts zinc diacrylate as a crosslinker and 0.2 to 0.8 parts of a free radical initiator. Up to 40 parts by weight zinc oxide or other inert filler to adjust weight is preferably also included. The polybutadiene preferably has a cis 1,4 content above about 40% and more preferably above about 90%.

In one typical way of forming a composition according to the present invention, the polybutadiene and zinc diacrylate are mixed together. When the components are initially mixed together the temperature of the mixture rises. The mixing is contained until a good dispersion is achieved as indicated by reaching a temperature of about 225° to 325° F. This is generally about 3 to 30 minutes. Once the mixing is complete the admixture is cooled to a temperature below the decomposition temperature of the free radical initiator. The initiator is added to the mixture, and the mixture is again mixed for about 3 to 15 minutes. The mass is then suitably milled into slabs or extruded into rods from which pieces are cut slightly larger and heavier than the desired golf ball product. These pieces are placed in a heated golf ball product mold such as a ball cup mold or a ball core mold and cured at elevated temperature under pressure. A temperature of about 280° F. to 340° F. for a period of about 15 to 30 minutes has been found to be suitable.

The pressure is not critical so long as it is sufficient to prevent the mold from opening during heating and curing.

Controlling the amount of the free radical initiator does not, of itself, necessarily make a good golf ball product. The golf ball product should have a suitable compression, typically from about 50 to about 110. Compression as used herein refers to PGA compression and is a well-known value in the golf ball industry. The golf ball should also not be over crosslinked. The method for determining whether or not there is over cross-linking is to measure the swell index. The swell index should be at least about 0.6 and is preferably above about 0.8. Swell index is measured by taking a weighed sample of the golf ball product, immersing it in toluene under ambient conditions for four days and then calculating the swell index according to the following formula:

$$\frac{\text{final weight} - \text{initial weight}}{\text{initial weight}} = \text{swell index}$$

In addition to the amount of free radical initiator and the amount of zinc diacrylate, the temperature of cure and the time of cure will also have an effect upon both the PGA compression and the swell index.

These and other aspects of the present invention may be more fully understood with reference to the following examples.

In the examples polybutadiene having a cis-1,4 polybutadiene content in excess of 90% was used. For each 100 parts of polybutadiene, 30 parts by weight of zinc diacrylate was used and 24 parts by weight of zinc oxide was included as a filler. Except where indicated, the free radical initiator in each case was α,α'-bis-(t-butylperoxy)diisopropyl benzene. The amount of free radical initiator is based on parts by weight per 100 parts by weight of polybutadiene.

EXAMPLE 1

A core of a two piece golf ball was made by curing the base composition with 1.1 parts free radical initiator at 320° F. for 20 minutes. The cores had a PGA compression of 98 and a swell index of about 0.3. The resulting cores were tested for durability by hitting them 50 times with an implement travelling at about 125 feet per second. Severe cracking of the cores occurred.

EXAMPLE 2

Example 1 was repeated except that in this instance the amount of free radical initiator was reduced to 0.2 parts. The resulting cores had a PGA compression of 68 and a swell index above 0.6. In the durability test, no cracking occurred.

EXAMPLE 3

Example 1 was repeated using 0.5 parts free radical initiator and a cure temperature of 300° F. The resulting golf balls had a PGA compression of 85 and a swell index of about 0.6. None of the balls cracked in the durability test.

EXAMPLE 4

Example 1 was repeated using 1.4 parts free radical initiator. The resulting cores had a PGA compression of 100 and a swell index of below 0.3. In the durability test, the cores exhibited severe cracking.

EXAMPLE 5

Example 1 was repeated except that the amount of free radical initiator was 0.2 parts and the cure temperature was 280° F. While the swell index was above 0.6 and the cores showed no cracking in the durability test, the cores were not considered suitable for use as a golf ball product because the PGA compression was 0.

EXAMPLE 6

Example 5 was repeated with the amount of free radical initiator being increased to 0.5 parts. In this case a core was obtained which had a swell index above 0.6, a PGA compression of 77 and the cores exhibited no cracking in the durability test.

EXAMPLE 7

Example 1 was repeated using 0.8 parts free radical initiator and a cure temperature of 300° F. The resulting cores had a swell index above 0.6 and a PGA compression of 94. In the durability test, no cracking of the cores occurred.

EXAMPLE 8

Examples 1–7 are repeated except that the free radical initiator employed is dicumyl peroxide. Comparable results are obtained.

EXAMPLE 9

Examples 1–7 are repeated except that one piece solid golf balls are made rather than golf ball cores. Comparable results are obtained.

EXAMPLE 10

The cores made in Examples 1–7 are enclosed in a golf ball cover. The golf ball cover is composed of Surlyn resin, a duPont trademark for an ionomer consisting of a copolymer of ethylene and methacrylic acid partially crosslinked by metal ions. The specific resin used is a combination of Surlyn 1702, Surlyn 1706 and Surlyn 1707 as set forth in U.S. Pat. No. 4,323,427. Acceptable golf balls are obtained in each instance except with the core of Example 5. However in the durability tests, golf balls made with cores of Examples 2, 3, 6 and 7 are found to be far more durable than golf balls made with cores of Examples 1 and 4. While there is a measurable PGA compression with the golf ball with the core of Example 5, it is found to be well below the 50 minimum necessary to have an acceptable golf ball.

It will be understood that the claims are intended to cover all changes and modifications of the preferred embodiments of the invention, herein chosen for the purpose of illustration, which do not constitute departure from the spirit and scope of the invention.

What is claimed is:

1. In the manufacture of a golf ball product by crosslinking polybutadiene with about 25 to 40 parts zinc diacrylate by weight per 100 parts by weight polybutadiene, the improvement comprising the use of about 0.2 to 0.8 parts by weight per 100 parts by weight polybutadiene of peroxide free radical initiator.

2. The manufacture of a golf ball product according to claim 1 wherein the free radical initiator is present in the amount of about 0.2 to 0.5 parts.

3. The manufacture of a golf ball product according to claim 1 wherein the free radical initiator is present in the amount of about 0.2 parts.

4. The manufacture of a golf ball product according to claim 1 wherein the golf ball product is the core of a two piece golf ball.

5. The manufacture of a golf ball product according to claim 4 wherein the cover of the two piece golf ball is composed of one or more ionomer resins.

6. The manufacture of a golf ball product according to claim 1 wherein the golf ball product is a one piece solid golf ball.

7. A method of making a golf ball product comprising admixing polybutadiene and, per 100 parts by weight polybutadiene, 30–40 parts by weight zinc diacrylate together with 0.2 to 0.8 parts by weight per 100 parts of polybutadiene of peroxide free radical initiator and curing the same at a temperature from about 280° F. to 320° F. for a period of about 15–30 minutes, the amount of zinc diacrylate and of free radical initiator and the temperature and time of cure being selected to yield a golf ball having a PGA compression of about 50–110 and a swell index of above about 0.6.

8. The method of claim 7 wherein the said swell index is above about 0.8.

9. The method of claim 7 wherein the amount of free radical initiator is from about 0.2 to 0.8 parts.

10. The method of claim 9 wherein the amount of zinc diacrylate is about 30 parts and the amount of free radical initiator is about 0.2 parts.

11. The method of claim 7 wherein the golf ball product is the core of a two piece golf ball.

12. The method of claim 7 wherein the golf ball product is a one piece solid golf ball.

13. The manufacture of a golf ball product according to claim 1 wherein the free radical initiator is selected from the group consisting of α,α′-bis-(t-butylperoxy)-diisopropyl benzene and dicumyl peroxide.

14. The manufacture of a golf ball product according to claim 2 wherein the free radical initiator is selected from the group consisting of α,α′-bis-(t-butylperoxy)-diisopropyl benzene and dicumyl peroxide.

15. The manufacture of a golf ball product according to claim 3 wherein the free radical initiator is selected from the group consisting of α,α′-bis-(t-butylperoxy)-diisopropyl benzene and dicumyl peroxide.

16. The method of claim 7 wherein the free radical initiator is selected from the group consisting of α,α′-bis-(t-butylperoxy)diisopropyl benzene and dicumyl peroxide.

17. The method of claim 9 wherein the free radical initiator is selected from the group consisting of α,α′-bis-(t-butylperoxy)diisopropyl benzene and dicumyl peroxide.

18. The method of claim 10 wherein the free radical initiator is selected from the group consisting of α,α′-bis-(t-butylperoxy)diisopropyl benzene and dicumyl peroxide.

19. The method of claim 7 wherein the amount of free radical initiator is from about 0.2 to about 0.5 parts.

20. The method of claim 19 wherein the free radical initiator is selected from the group consisting of α,α′-bis-(t-butylperoxy)diisopropyl benzene and dicumyl peroxide.

21. A golf ball product made by the method of claim 7.

22. A golf ball product made by the method of claim 8.

23. A golf ball product made by the method of claim 10.

24. A golf ball product made by the method of claim 11.

25. A golf ball product made by the method of claim 16.

26. A golf ball product made by the method of claim 18.

27. A golf ball product made by the method of claim 9.

28. A golf ball product made by the method of claim 20.

29. A method of making a product comprising admixing polybutadiene and, per 100 parts by weight polybutadiene, 30–40 parts by weight zinc diacrylate together with 0.2 to 0.8 parts by weight per 100 parts of polybutadiene of peroxide free radical initiator and curing the same at a temperature from about 280° F. to 320° F. for a period of about 15–30 minutes, the amount of zinc diacrylate and of free radical initiator and the temperature and time of cure being selected to yield a product having a swell index of above about 0 6.

30. The method of claim 29 wherein the said swell index is above about 0.8.

31. The method of claim 29 wherein the amount of free radical initiator is from about 0.2 to 0.8 parts.

32. The method of claim 29 wherein the amount of free radical initiator is from about 0.2 to about 0.5 parts.

33. The method of claim 31 wherein the amount of zinc diacrylate is about 30 parts and the amount of free radical initiator is about 0.2 parts.

34. The method of claim 29 wherein the free radical initiator is selected from the group consisting of α,α′-bis-(t-butylperoxy)diisopropyl benzene and dicumyl peroxide.

35. The method of claim 31 wherein the free radical initiator is selected from the group consisting of α,α′-bis-(t-butyperoxy)diisopropyl benzene and dicumyl peroxide.

36. The method of claim 32 wherein the free radical initiator is selected from the group consisting of α,α′-bis-(t-butylperoxy)diisopropyl benzene and dicumyl peroxide.

37. The method of claim 33 wherein the free radical initiator is selected from the group consisting of α,α′-bis-(t-butylperoxy)diisopropyl benzene and dicumyl peroxide.

38. A product made by the method of claim 29.

39. A product made by the method of claim 30.

40. A product made by the method of claim 32.

41. A product made by the method of claim 33.

42. A product made by the method of claim 34.

43. A product made by the method of claim 36.

44. A product made by the method of claim 37.

45. A golf ball product manufactured according to claim 1.

46. A golf ball product manufactured according to claim 2.

47. A golf ball product manufactured according to claim 3.

48. A golf ball product manufactured according to claim 4.

49. A golf ball product manufactured according to claim 5.

50. A golf ball product manufactured according to claim 6.

51. A golf ball product manufactured according to claim 13.

52. A golf ball product manufactured according to claim 14.

53. A golf ball product manufactured according to claim 15.

54. In the manufacture of a product by crosslinking polybutadiene with about 25 to 40 parts zinc diacrylate by weight per 100 parts by weight polybutadiene, the improvement comprising the use of about 0.2 to 0.8 parts by weight per 100 parts by weight polybutadiene of peroxide free radical initiator.

55. The manufacture of a product according to claim 54 wherein the free radical initiator is present in the amount of about 0.2 to 0.5 parts.

56. The manufacture of a product according to claim 54 wherein the free radical initiator is present in the amount of about 0.2 parts.

57. The manufacture of a product according to claim 54 wherein the free radical initiator is selected from the group consisting of α, α'-bis-(t-butylperoxy)diisopropyl benzene and dicumyl peroxide.

58. The manufacture of a product according to claim 55 wherein the free radical initiator is selected from the group consisting of α,α'-bis-(t-butylperoxy)diisopropyl benzene and dicumyl peroxide.

59. The manufacture of a product according to claim 56 wherein the free radical initiator is selected from the group consisting of α,α'-bis-(t-butylperoxy)diisopropyl benzene and dicumyl peroxide.

60. A product manufactured according to claim 54.

61. A product manufactured according to claim 55.

62. A product manufactured according to claim 56.

63. A product manufactured according to claim 57.

64. A product manufactured according to claim 58.

65. A product manufactured according to claim 59.

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 4,770,422

DATED : September 13, 1988

INVENTOR(S) : Sharon R. Isaac

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Column 6, line 8, change the dependency of the claim from "claim 9" to --claim 19--.

Signed and Sealed this

Twenty-first Day of February, 1989

Attest:

Attesting Officer

DONALD J. QUIGG

Commissioner of Patents and Trademarks

EXHIBIT 9

REDACTED